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FROM : Oleg F. Kaplun, Esq.
Fay Kaplun & Marcin, LLP

DATE : March 30, 2006

SUBJECT : Endoscopy
U.S. Patent Appln. Serial No. 10/674,512
for *Through the Scope Tension Member Release Clip*
Our Ref.: 10121/03501

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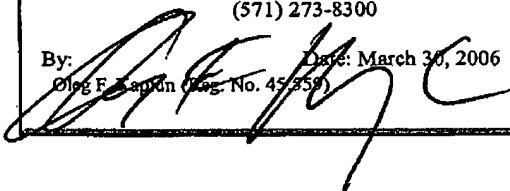
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Wells et al.
Serial No. : 10/674,512
Filed : September 30, 2003
For : Through the Scope Tension Member Release Clip
Group Art Unit : 3739
Examiner : Matthew J. Kasztejna

Mail Stop: Appeal Brief-Patent
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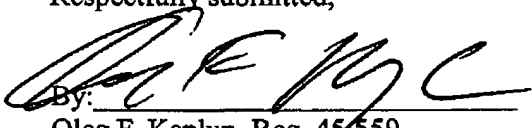
By:  Date: March 30, 2006
Oleg F. Kaplun (Reg. No. 45,559)

TRANSMITTAL

Transmitted herewith please find a Reply Brief in response to the Examiner's Answer mailed on January 30, 2006 for filing in the above-identified application. No fees are believed to be required. The Commissioner is hereby authorized to charge any additional required fees to the Deposit Account of Fay Kaplun & Marcin, LLP No. 50-1492. A copy of this paper is enclosed for that purpose.

Respectfully submitted,

Dated: March 30, 2006

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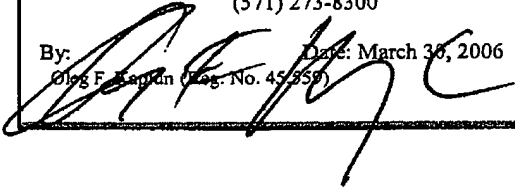
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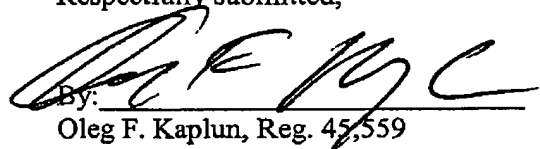
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REPLY BRIEF UNDER 37 C.F.R. § 41.41

In response to the Examiner's Answer mailed January 30, 2006 to the Appeal Brief filed August 16, 2005, and pursuant to 37 C.F.R. § 41.41, appellants present this reply brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1-5, 10, 11, 15, 17 and 18 in the final Office Action dated May 11, 2005, clarified in the Advisory Action of August 3, 2005 and further clarified in the Examiner's Answer mailed January 30, 2006. The appealed claims are set forth in the attached Claims Appendix.

Serial No.: 10/674,512
Group Art Unit: 3739
Attorney Docket No.: 10121/03501

1. Grounds of Rejection to be Reviewed on Appeal

- I. Whether claims 1, 2, 4-5, and 15 are unpatentable under 35 U.S.C. § 102(a) as anticipated by U.S. Patent Publication No. 2003/0069592 to Adams et al. ("Adams")
- II. Whether claims 3, 10-11, and 17-18 are unpatentable under 35 U.S.C. § 103(a) as obvious over Adams in view of U.S. Patent No. 6,814,742 to Kimura et al. ("Kimura")

2. Argument

- I. The Rejection of Claims 1, 2, 4-5, and 15 Under 35 U.S.C. § 102(a) as Anticipated by Adams Should be Reversed

A. The Examiner's Rejection

In the Examiner's Answer, the Examiner recites the language of the final rejection verbatim stating that Adams discloses an apparatus providing a first feedback indicating a decision configuration of a hemostatic clip and a second feedback indicating separation of the hemostatic clip from a shaft. *1/30/06 Examiner's Answer*, p. 6.

Claim 1 recites an apparatus for deployment of a hemostatic clip comprising "a handle assembly" and "a shaft connected to a distal portion of the handle assembly" in combination with "a clip assembly releasably coupled to a distal portion of the shaft, the clip assembly including clip arms and a capsule cooperating with the clip arms to provide a first user feedback indicating a decision configuration of the clip assembly" and "*a control wire including a ball connector, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft.*"

In contrast, Adams describes a medical device for deploying a hemostatic clip 1201 operating as follows (shown in Figs. 12a and 12b):

Serial No.: 10/674,512
Group Art Unit: 3739
Attorney Docket No.: 10121/03501

- Clip 1201 gathers a blood vessel between its arms
- Control wire 1207, using a ball 1202 fitted into compressed socket tabs 1203 of the clip 1201, pulls the clip 1201 proximally through an outer sleeve 1204 compressing the arms of the clip 1201 on the blood vessel
- When socket tabs 1203 reach cut-outs 1205 in the outer sleeve 1204, the socket tabs 1203 move outward into the cut-outs 1205 releasing the ball 1202 (and the control wire 1207) from the clip 1201 *while leaving the clip 1201 and the outer sleeve 1204 attached to the sheath 1206*
- The sheath 1206 is then pulled proximally to detach the outer sleeve 1204 from the sheath 1206, leaving the outer sheath 1204 and the clip 1201 in place on the blood vessel.

Adams, ¶ [0084].

The Examiner states that a second feedback indicating separation of the clip 1201 and shaft is provided by the lack of tension on the control wire 1207. *1/30/06 Examiner's Answer*, p. 6. However, as understood from the above description of Adams, release of the ball 1202 from the socket tabs 1203, and any slack on the control wire 1207 resulting therefrom, only indicates that the clip 1201 has closed. As described above, the clip 1201 and the outer sheath 1204 are still coupled to the sheath 1206 at this point. Separating the clip 1201 from the sheath 1206 of Adams requires a separate step -- i.e., pulling the sheath 1206 proximally to detach it from the outer sleeve 1204 (and the clip 1201). This has nothing to do with either the control wire 1207 or the ball 1202 which have already been separated from the outer sheath 1204 and the clip 1201.

Therefore, appellants respectfully submit that Adams neither discloses nor suggests "a control wire including a ball connector, the control wire extending from the handle

Serial No.: 10/674,512
Group Art Unit: 3739
Attorney Docket No.: 10121/03501

assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, *wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft,*" as recited in claim 1. Thus, it is respectfully requested that the Board reverse the rejection of claim 1 and the claims (2, 4, 5 and 15) which depend therefrom.

II. The Rejection of Claims 3, 10-11, and 17-18 Under
35 U.S.C. § 103(a) as Obvious over Adams in view
of Kimura Should Be Reversed

A. The Examiner's Rejection

The deficiencies of Adams have been discussed above, and it is respectfully submitted that Kimura does not cure these deficiencies. In particular, Kimura teaches a clip mounting device 5 utilizing a claw hook 3a to pull an arrowhead hook 3b of a clip 2 to clip a target tissue. Kimura never shows or suggests a control wire with a ball connector. Thus, Kimura does not disclose or suggest "a control wire including a ball connector, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, *wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft,*" as recited in claim 1. Thus, because claims 3, 10-11, and 17-18 depend from, and, therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are allowable for the reasons discussed above in regard to claim 1 and that the Board should reverse this rejection.

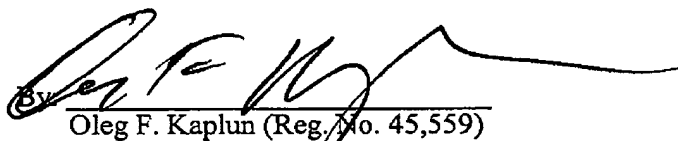
Serial No.: 10/674,512
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Attorney Docket No.: 10121/03501

3. Conclusions

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. §§ 102(a) and 103(a), and indicate that claims 1-5, 10, 11, 15, 17 and 18 are allowable.

Respectfully submitted,

Date: March 30, 2006


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Serial No.: 10/674,512
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Attorney Docket No.: 10121/03501

CLAIMS APPENDIX

1. Apparatus for deployment of a hemostatic clip comprising:
 - a handle assembly;
 - a shaft connected to a distal portion of the handle assembly;
 - a clip assembly releasably coupled to a distal portion of the shaft, the clip assembly including clip arms and a capsule cooperating with the clip arms to provide a first user feedback indicating a decision configuration of the clip assembly; and
 - a control wire including a ball connector, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft.
2. The apparatus according to claim 1, further comprising an over sheath movable between a first position covering the shaft and the clip assembly and a second position uncovering the clip assembly.
3. The apparatus according to claim 2, further comprising an over sheath stop engageable on the shaft to prevent movement of the over sheath to the second position.
4. The apparatus according to claim 1, wherein the clip arms further comprise stop shoulders engaging a distal end of the capsule to provide the first user feedback during proximal movement of the control wire.

5. The apparatus according to claim 1, wherein the decision configuration indicates a position of the control wire beyond which further proximal movement of the control wire precludes return of the clip arms to an open configuration by a reversed movement of the control wire.

10. The apparatus according to claim 9, wherein the separation tension is at least approximately 4 lbf.

11. The apparatus according to claim 9, wherein the separation tension is less than approximately 12 lbf.

15. The apparatus according to claim 1, wherein the first feedback includes a tactile and aural feedback.

17. The apparatus according to claim 16, wherein the yield tension is greater than the separation tension.

18. The apparatus according to claim 16, wherein the yield tension is between approximately 10 lbf and 20 lbf.

Serial No.: 10/674,512
Group Art Unit: 3739
Attorney Docket No.: 10121/03501

EVIDENCE APPENDIX

No evidence has been entered or relied upon in the present appeal.

Serial No.: 10/674,512
Group Art Unit: 3739
Attorney Docket No.: 10121/03501

RELATED PROCEEDING APPENDIX

No decisions have been rendered regarding the present appeal or any proceedings related thereto.